

Guidance for Industry and for FDA Staff

**GUIDANCE FOR REQUEST AND
ISSUANCE OF INTERIM NOTICE
LETTERS FOR MAMMOGRAPHY
FACILITIES UNDER THE
MAMMOGRAPHY QUALITY
STANDARDS ACT, 42 U.S.C. § 263(b)**

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**U.S. Department of Health and Human Services
Food and Drug Administration
Center for Devices and Radiological Health**

**Mammography Standards Branch
Division of Mammography Quality and Radiation Programs
Office of Health and Industry Programs**

Preface

Public Comment

Comments and suggestions may be submitted at any time for Agency consideration to, Mammography Standards Branch, HFZ-240, 1350 Piccard Drive, Rockville, MD 20850. Comments may not be acted upon by the Agency until the document is next revised or updated. For questions regarding the use or interpretation of this guidance contact Vickie Jernigan at (301) 594-3772, or by electronic mail at vxj@cdrh.fda.gov.

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World Wide Web/CDRH/DMQRP home page: <http://www.fda.gov/cdrh/dmgrp.html>, or CDRH Facts on Demand at 1-800-899-0381 or 301-827-0111, specify number 2217 when prompted for the document shelf number.

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MAMMOGRAPHY FACILITIES UNDER THE MAMMOGRAPHY QUALITY
STANDARDS ACT, 42 U.S.C. § 263(b)**

**UNITED STATES FOOD AND DRUG ADMINISTRATION
CENTER FOR DEVICES AND RADIOLOGICAL HEALTH
OFFICE OF HEALTH AND INDUSTRY PROGRAMS
DIVISION OF MAMMOGRAPHY QUALITY AND RADIATION PROGRAMS**

INTRODUCTION

This guidance document reflects the agency's current thinking on the procedures to be used by FDA to issue, and by approved accreditation bodies to request, interim notice letters for mammography facilities, under the Mammography Quality Standards Act of 1992 (MQSA or the Act). It does not create or confer any rights for or on any person and does not operate to bind FDA or the public. An alternative approach may be used if such approach satisfies the requirements of the applicable statute, regulations, or both.

Enforcement of MQSA is governed by regulations at 21 CFR Part 900. The regulations, at section 900.11, require that mammography facilities be accredited by an FDA approved accreditation body in order to be certified by FDA to perform mammography. Whenever a mammography facility is accredited or reaccredited, the accreditation body notifies FDA electronically via the Certification and Accreditation Support System (CASS) and FDA then issues a certificate to the facility. Under circumstances described below, there may be a delay in issuing a certificate or completing the reaccreditation process beyond the facility's certificate expiration date. In such cases FDA may issue a one-time interim notice letter to a facility. The interim notice authorizes the facility to perform mammography until the facility receives its certificate, or it completes the reaccreditation process. An interim notice is valid for not more than 45 days.

If a facility's certificate is about to or has expired and the facility does not qualify for an interim notice, the facility may be reinstated in accordance with its accreditation body's policies.

CIRCUMSTANCES UNDER WHICH FDA MAY ISSUE INTERIM NOTICES

To apply for an interim notice, a facility should submit its request to its accreditation body. The accreditation body will forward the request, with its recommendation, to FDA within 2 business days after receipt. In all cases the following criteria should be used by FDA to determine whether an interim notice should be issued to a facility.

FDA may issue an interim notice to a mammography facility under the following two sets of circumstances:

1. **CERTIFICATE DELAY:** There may be a delay in issuing or delivering a certificate to a facility that has met the requirements for a provisional or provisional reinstatement

certificate, or has completed accreditation or reaccreditation and the facility's certificate has or is about to expire.

2. REACCREDITATION COMPLETION DELAY: There may be a delay in completing reaccreditation beyond the expiration date of a facility's certificate for various reasons such as a delay in completion of the clinical image review. For a facility to be eligible to receive an interim notice, all of the following criteria should be met:
 - a) the facility has an expired or expiring three year FDA Mammography Facility Certificate,
 - b) the reaccrediting facility has applied for reaccreditation in a timely manner, i.e., at least six months prior to the expiration date of its certificate. Facilities receive ample notice from their AB's that they should apply for reaccreditation seven to nine months prior to expiration of their accreditation. FDA considers six months prior to certificate expiration to be a minimum time frame that is adequate for reaccreditation;
 - c) the facility has shown a good faith effort in completing the reaccreditation process in a timely manner, i.e., submitted its clinical images and other information in time to complete normal review within the six month reaccreditation window; and
 - d) the delay should not otherwise be due to inappropriate facility activities.

PROCEDURES FOR ACCREDITATION BODIES TO REQUEST INTERIM NOTICES

All requests should be sent to FDA by electronic mail. To be processed in a timely manner, the requests should contain the following information in the following order.

1. Identification of the request as either:
 - a) CERTIFICATE DELAY: and provide the intended date of transmission of the data record for a newly accredited, reaccredited or reinstated facility, or
 - b) REACCREDITATION DELAY: and provide the reason for the anticipated delay in completing reaccreditation that may extend beyond the facility's certificate expiration date. **If the facility has applied for reaccreditation less than six months prior to expiration of its certificate an interim notice should not be requested.**
2. FDA ID number (or accreditation body identification number for a new facility)
3. Name and address of the facility
4. Name of contact person at the facility

5. FAX number of the facility
6. Phone number of the facility
7. Date of expiration of current certificate
8. Date that the facility applied for reaccreditation

Upon receipt of this information, FDA should determine whether or not the issuance of an interim notice is appropriate, and if so, an interim notice letter may be sent to the facility by facsimile. FDA may contact the accreditation body and request additional information while making the determination.